

REMARKS**A. Summary of the Interview**

Applicants thank Examiner Liu for the courtesy extended to their representatives, Joseph D. Eng Jr. and Kenneth H. Sonnenfeld, during their interview with the Examiner at the U.S. Patent and Trademark Office on May 24, 2011. During the interview, the Examiner and Applicants' representatives discussed the pending rejections and possible claim amendments.

B. Status of the Claims

Prior to the submission of this paper, claims 78-80, 84, 85, 88, and 90-97 were pending in this application. In this response, Applicants have amended claims 78 and 90, and requested the cancellation of claims 84 and 85. Also, claim 95 is withdrawn by the Examiner, as well as aspects of claim 91 directed to the botulinum toxin serotypes B, C, D, E, F, and G (as directed to non-elected inventions based on Applicants' election of October 5, 2010).

Accordingly, claims 78-80, 88, 90-94 and 96-97 are under examination, as they relate to botulinum toxin type A.

Claims 79, 80, 84, 85, 88, 90-97 are rejected under 35 U.S.C. § 112, ¶ 2 for allegedly lacking antecedent basis.

Claims 78-80, 84, 88, 90, 93, 94, 96, and 97 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by International Application No. WO 0207773 to Waugh et al. ("Waugh '773")

Claims 78-80, 84, and 88 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by International Application No. WO200162297 to Rothbard et al. ("Rothbard").

Claims 78-80 and 85 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over Waugh in view of U.S. Pre-Grant Publication No. 20030109448 to Crowley et al. (“Crowley”).

Claim 78-80, 90, 91 and 92 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over Waugh in view of EP 1421948 to Aoki et al. (“Aoki”).

Claims 78-80 and 85 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over Rothbard, in view of Crowley and Waugh.

Claims 78-80, 84, 85, 90-94, 96 and 97 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 67-70 and 72 of U.S. Application No. 10/591,486.

Claims 78-80, 84, 85, 90-94 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 28-30 and 33 of U.S. Application No. 12/897,188.

Claims 78-80, 84, 85, 88, 90-94, 96, and 97 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 51-54, 64, 77, 78, 80, and 110 of U.S. Application No. 10/591,732.

Claims 78-80, 84, 85, 90-94, 96, and 97 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9, 13-16, and 21-24 of U.S. Application No. 11/816,602.

Claims 78-80, 84, 85, 90-94, 96, and 97 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 15 of U.S. Application No. 11/954,885.

Claims 78-80, 84, 85, 90-94, 96, and 97 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 15 of U.S. Application No. 12/520,964.

Claims 78-80, 84, 85, 90-94, 96, and 97 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 and 9 of U.S. Application No. 12/647,677.

In addition, the Examiner objects to the specification and drawings for various informalities.

C. Explanation of the Amendments

Claims 78 and 90 are amended herein, as are the specification and drawings. The amendments introduce no new matter, as detailed below.

1. Amendments to the Claims

Claim 78 is amended to recite “a composition comprising” a protein in conjunction with an effective amount of a positively charged carrier, the positively charged carrier comprising a positively charged backbone having attached positively charged efficiency groups; wherein the carrier and the biologically active protein “directly contact to form a non-covalent complex” Support for these amendments occurs throughout the specification and original claims, e.g., in paragraph [0029], which states that “[i]n all aspects of the present invention, the association between the carriers and the biologically active agent is by non-covalent interaction, which can include, for example, ionic interactions, hydrogen bonding, van der Waals forces, or combinations thereof.” Support also occurs, e.g., in paragraph [0045], where it is stated that “...

certain substances can be transdermally delivered by use of certain positively charged carriers alone, without requiring the inclusion of a negative backbone.” This passage in paragraph [0045] also provides support for the phrase “wherein the biologically active protein is not modified by covalent attachment to a negatively charged backbone.” The absence of an intervening negative backbone component indicates a direct contact between the carrier and the biologically active protein. Furthermore, further support direct contact between the carrier and a biologically active protein is provided by Figures 1 and 2.

Claim 78 also is amended to specify that the carrier comprises “positively charged backbone comprises a member selected from the group consisting of polyalkylencimine, a positively charged polypeptide, a peptoid, an electronic mimic of a polypeptide and a steric mimic of a polypeptide; wherein the positively charged efficiency groups are amino acid sequences selected from the group consisting of (gly)_p-RGRDDRRQRRR-(gly)_q, (gly)_p-YGRKKRRQRRR-(gly)_q, (gly)_p-RKKRRQRRR-(gly)_q, (gly)_{n1}-(gly)_{n2}, gly₃-arg₇, GGRKKRRQRRR, and (gly)_{n3}-(arg)_{n4}, wherein the subscripts p and q are independently an integer from 0 to 20, wherein n1 is an integer from 0 to 20 and n2 is an odd integer from about 5 to about 25, and wherein n3 is an integer from 3 to about 5 and n4 is an odd integer from about 7 to about 17.” Support for these amendments occurs throughout the specification and original claims, e.g., at paragraphs [0055] to [0062].

Claim 78 has also been amended to replace the term “branching group” with “efficiency group.” Support for this amendment is found in paragraph [0045].

Claim 79 is amended merely to replace “agent” with “biologically active protein.”

Claim 90 is amended merely to recite “biologically active protein,” in accordance with the language of claim 80, from which it depends.

Accordingly, there are no issues of new matter concerning the current amendments.

2. Amendments to the Specification

The specification is amended herein to provide, in the Brief Description of the Drawings, the meanings for certain terms that appear in the Figures. Support for these amendments can be found in the specification and original claims as follows:

- paragraph [0140] describes the terms “AK1”, “AL1”, and AM1” of Figures 3-4;
- paragraph [0150] describes the terms “AK1” and AL1” of Figure 5;
- paragraph [0137] describes the terms “AS”, “AT”, and “AU” of Figure 6;
- paragraphs [0165] and [0170] describes the term “EB-btox” of Figure 7; and
- paragraphs [0163] and [0170] describe the term “nl” of Figure 7.

Finally, Applicants replace “Figure 9” with “Figure 9A to 9D”, which reflects the labels used in the original figures.

Accordingly, there also are no issues of new matter with respect to the amended specification.

3. Amendments to the Figures

Applicants submit herein Replacement Figures, correcting terms that appear along the x-axis in Figure 5 and inserting the label “Figure 8”. The correct terms appear in the specification, e.g., at paragraph [0150], while the “Figure 8” label appears at paragraph [0042].

Accordingly, there also are no issues of new matter with respect to the Replacement Figures.

D. Objections to the Application

The Examiner objects to certain alleged informalities in the brief description and drawing of the specification.

1. Objections to the Specification

The Examiner objects to the specification in that the Brief Description of the Drawings allegedly does not provide the meanings of certain terms in the Figures. Specifically, the Examiner notes that the brief description of Figures 3 and 4, at paragraph [0038], does not indicate the meanings of the terms “AL1”, “AK1”, and “AM1”; and a similar objection is directed to the terms “AL” and “ALK” in Figure 5; “AS”, “AT”, and “AU” in Figure 6; and “EB-btox” and “NI” in Figure 7.

The Examiner further objects to the recitation of “Figure 9”, at paragraph [0043], line 1, which the Examiner states should read “Figure 9A to 9D” instead.

Without acquiescence, Applicants have amended the specification and Figures, as noted above, to provide meanings of terms used in the Figures and to recite “Figure 9A to 9D”.

Accordingly, Applicants respectfully submit, the objections to the specification are rendered moot.

2. Objections to the Drawings

The Examiner objects to the drawings Applicants submitted on September 1, 2006, for allegedly omitting the label “Figure 8”. Without acquiescence, Applicants herewith submit a set of corrected drawings, including this label and also correcting terms in Figure 5, as discussed above.

Accordingly, Applicants respectfully submit, the objections to the drawings are rendered moot.

E. The Pending Claims are Not Indefinite

As noted above, claims 79, 80, 84, 85, 88, 90-97 are rejected under 35 U.S.C. § 112, ¶ 2 for allegedly lacking antecedent basis. Without acquiescence, Applicants have canceled claim 85 and amended claims 78 and 90 such that there are no outstanding issues regarding proper antecedent basis.

Accordingly, Applicants respectfully submit, the rejections under § 112, ¶ 2 should be withdrawn.

F. The Pending Claims Are Novel Over Waugh

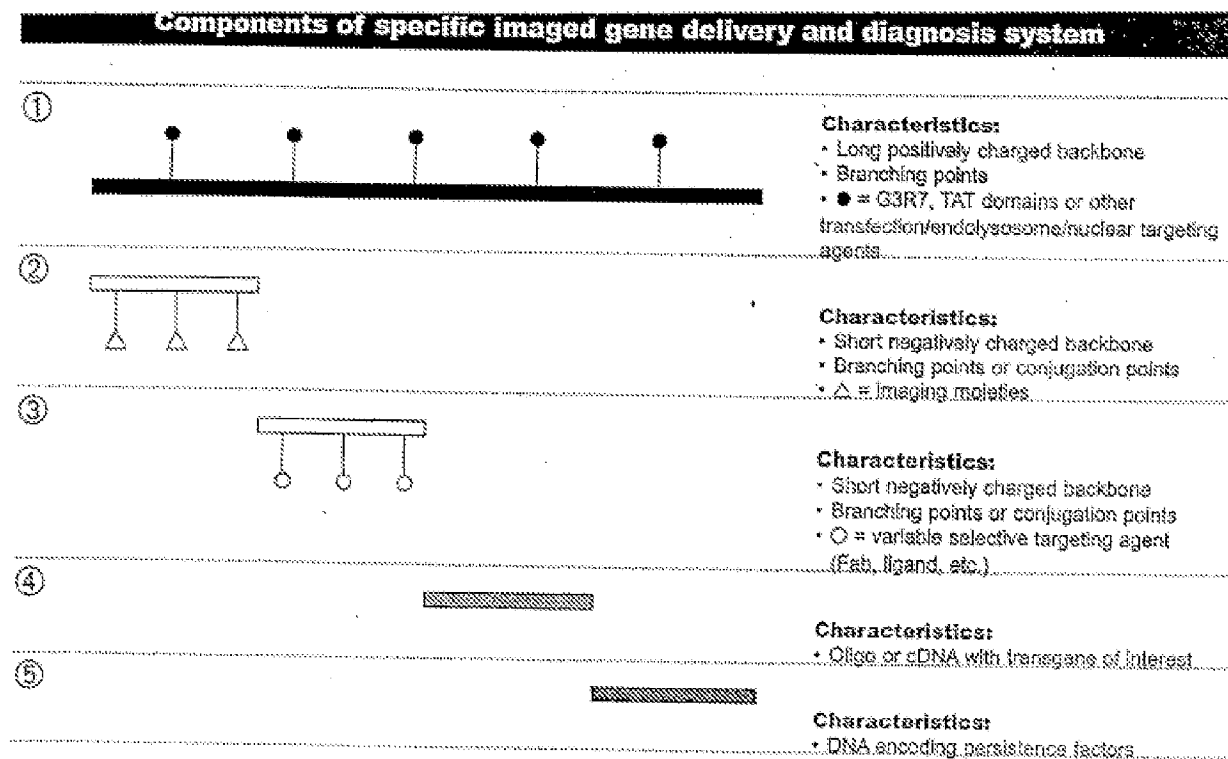
Applicants respectfully traverse the rejection of claims 78-80, 84, 88, 90, 93, 94, 96, and 97 under 35 U.S.C. §102(b) for allegedly being anticipated by Waugh. Waugh fails to disclose all of the features recited in Applicants' presently pending claims. Accordingly, the rejection should be withdrawn. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (stating that claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference).

Claim 78 of the present application requires "a biologically active protein" and "a positively charged carrier", which comprises "a positively charged backbone having attached positively charged efficiency groups" Furthermore, claim 78, as amended, requires that "the biologically active protein is not modified by covalent attachment to a negatively charged

backbone and the carrier and the biologically active protein directly contact to form a non-covalent complex; ” and also that the biologically active protein “is not insulin.” The remaining claims facing this rejection, claims 79-80, 88, 90, 94, 96, and 97, each depend directly or indirectly from claim 78, thus also requiring these features.

In contrast, Waugh does not disclose a composition where the biologically active protein “is not insulin” and where “the biologically active protein is not modified by covalent attachment to a negatively charged backbone and the carrier and the biologically active protein directly contact to form a non-covalent complex,” as required by the presently-amended claims. In Waugh, both cosmeceutical and therapeutic agents are described as “biological agents.” *See, e.g.,* Waugh, page 3, lines 32-33, page 15, line 20. Such biological agents include “biologically active proteins”, as Waugh lists a number of biologically active proteins as examples of such. *See, e.g.,* Waugh, page 15, lines 33-34. Critically, to the extent that “biological agents” are present in Waugh’s compositions, and are not insulin, ***they are attached to a negatively charged backbone.***

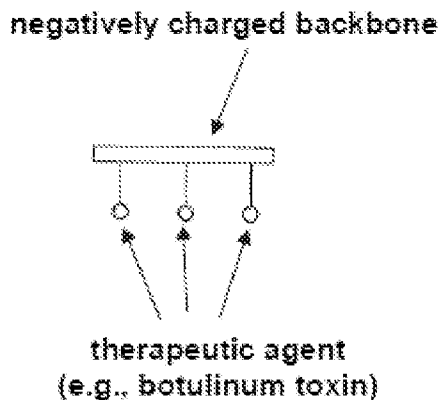
For example, in the “Summary of the Invention” section, Waugh states that its compositions comprise “a third negatively charged backbone having a plurality of attached biological agents.” Waugh, page 3, lines 28-29. Furthermore, this arrangement is illustrated in Figure 1 of Waugh, an excerpt of which is reproduced below:



As stated in Waugh's specification, Figure 1 shows that the therapeutic agents (e.g., biologically active proteins) are attached to "a short negatively charged backbone":

In this figure, the components are shown as (1) a solid backbone having attached positively charged groups (also referred to as efficiency groups shown as darkened circles attached to a darkened bar), for example $(\text{Gly})_{n1}-(\text{Arg})_{n2}$ (wherein the subscript $n1$ is an integer of from 3 to about 5, and the subscript $n2$ is an odd integer of from about 7 to about 17) or TAT domains; (2) a short negatively charged backbone having attached imaging moieties (open triangles attached to a light bar); (3) *a short negatively charged backbone having attached targeting agents and/or therapeutic agents (open circles attached to a light bar)*; (4) an oligonucleotide, RNA, DNA or cDNA (light cross hatched bar); and (5) DNA encoding persistence factors (dark cross hatched bar).

Waugh, pages 5-6. In other words, the attachment between the short negatively charged backbone and the therapeutic agents (e.g., biologically active proteins) is represented by the structure associated with reference numeral 3 in Figure 1, as reproduced below with annotations:



Waugh states that the use of negatively charged backbones with therapeutic agents and other components allows the formation of complexes with a positively charged backbone without the need to precisely position the therapeutic agent on a particular location on the positively charged backbone:

By placing these components on a negatively charged backbone, the invention obviates the need for attaching components in precise locations on a positive backbone as employed in other strategies (increasing complexity and expense and decreasing efficiency to a level that no successful combination has yet been reported due to steric limitations).

Waugh, page 5. Thus, the formation of Waugh's complexes that contain biological agents (such as a biologically active protein excluding insulin) *is mediated by the interaction between the positive and negative charges on the positively charged backbone and negatively charged backbone, respectively.* Accordingly, Waugh does not disclose a composition where "the biologically active protein is not modified by covalent attachment to a negatively charged backbone and the carrier and the biologically active protein directly contact to form a non-covalent complex," and where the biologically active protein "*is not insulin*", as required by the present claims (emphases added).

Because Waugh does not disclose all of the features recited in the present claims, the rejection of claims 78-80, 84, 88, 90, 94, 96, and 97 under 35 U.S.C. § 102(b) should be withdrawn. Applicants therefore respectfully request reconsideration and withdrawal of this ground of rejection.

G. The Pending Claims Are Novel Over Rothbard

Applicants respectfully traverse the rejection of claims 78-80, 84, and 88 under 35 U.S.C. §102(b) for allegedly being anticipated by Rothbard. Rothbard fails to disclose all of the features recited in Applicants' presently pending claims. Accordingly, the rejection should be withdrawn. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (stating that claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference).

Claim 78 of the present application requires the positively charged carrier to have attached positively charged efficiency groups that are "amino acid sequences selected from the group consisting of (gly)_p-RGRDDRRQRRR-(gly)_q, (gly)_p-YGRKKRRQRRR-(gly)_q, (gly)_p-RKKRRQRRR-(gly)_q, (gly)_{n1}-(gly)_{n2}, gly₃-arg₇, GGGRKKRRQRRR, and (gly)_{n3}-(arg)_{n4}, wherein the subscripts p and q are independently an integer from 0 to 20, wherein n1 is an integer from 0 to 20 and n2 is an odd integer from about 5 to about 25, and wherein n3 is an integer from 3 to about 5 and n4 is an odd integer from about 7 to about 17." The remaining claims facing this rejection, claims 79-80, 84, and 88, each depend directly or indirectly from claim 78, thus also requiring these features.

In contrast, Rothbard does not disclose a composition with a positively charged carrier having the positively charged efficiency groups that comprise the sequences recited above. Indeed, the so-called branching group that the Examiner points to in Rothbard is the side-chain of the amino acid, not an “efficiency group” which is defined in the claims as “amino acid sequences selected from the group consisting of (gly)_p-RGRDDRRQRRR-(gly)_q, (gly)_p-YGRKKRRQRRR-(gly)_q, (gly)_p-RKKRRQRRR-(gly)_q, (gly)_{n1}-(gly)_{n2}, gly₃-arg₇, GGGRKKRRQRRR, and (gly)_{n3}-(arg)_{n4}, wherein the subscripts p and q are independently an integer from 0 to 20, wherein n1 is an integer from 0 to 20 and n2 is an odd integer from about 5 to about 25, and wherein n3 is an integer from 3 to about 5 and n4 is an odd integer from about 7 to about 17,” as required by the currently-amended claims.

Because Rothbard does not disclose all of the features recited in the present claims, the rejection of claims 78-80, 84, and 88 under 35 U.S.C. § 102(b) should be withdrawn. Applicants therefore respectfully request reconsideration and withdrawal of this ground of rejection.

H. The Pending Claims Are Patentable Over Waugh in view of Crowley

Applicants respectfully traverse the rejection of claims 78-80 and 85 under 35 U.S.C. § 103(a) for allegedly being unpatentable over Waugh in view of Crowley. To establish *prima facie* obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art. See, e.g., *In re Royka*, 490 F.2d 981, 985 (CCPA 1974).

As an initial matter, Applicants note that claim 85 is cancelled, without any prejudice or disclaimer, thus rendering the rejection of claim 85 moot. With respect to claims 78-80, Waugh, as discussed above, fails to teach or suggest all of the features recited in Applicants’ presently pending claims. For instance, Waugh fails to teach or suggest a method that involves topically

applying the presently claimed carrier and biologically active protein, wherein the “carrier and the biologically active protein directly contact to form a non-covalent complex with the biologically active protein “ and wherein the biologically active protein “is not modified by covalent attachment to a negatively charged backbone.”

Crowley does supply these missing features. Crowley is directed to methods of promoting uptake and nuclear accumulation of polyamides in eukaryotic cells, and is cited by the Examiner for teaching separate administration of a molecular trafficking compound and the polyamide (allegedly at paragraph [0057] of Crowley). However, Crowley also fails to teach or suggest a method that involves topically applying the presently claimed carrier and biologically active protein, wherein the “carrier and the biologically active protein directly contact to form a non-covalent complex with the biologically active protein “ and wherein the biologically active protein “is not modified by covalent attachment to a negatively charged backbone.”

Accordingly, Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

I. The Pending Claims Are Patentable Over Waugh in view of Aoki.

Applicants respectfully traverse the rejection of claims 78-80, 90, and 91-92 under 35 U.S.C. § 103(a) for allegedly being unpatentable over Waugh in view of Aoki. To establish *pima facie* obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art. See, e.g., *In re Royka*, 490 F.2d 981, 985 (CCPA 1974).

Waugh, as discussed above, fails to teach or suggest “a method that involves topically applying the presently claimed carrier and biologically active protein, wherein the “carrier and the biologically active protein directly contact to form a non-covalent complex with the

biologically active protein “ and wherein the biologically active protein “is not modified by covalent attachment to a negatively charged backbone.”

Aoki fails to supply these missing features. Aoki is directed to the use of botulinum toxins for treating sweating in humans, and is cited by the Examiner for teaching different serotypes or forms of botulinum toxin (allegedly at paragraphs [0014] and [0027] of Aoki). These teachings, however, Applicants respectfully submit, in no way supply the missing features of Waugh. Nowhere in Aoki is there any teaching or suggest of a method that involves topically applying the presently claimed carrier and biologically active protein, wherein the “carrier and the biologically active protein directly contact to form a non-covalent complex with the biologically active protein “ and wherein the biologically active protein “is not modified by covalent attachment to a negatively charged backbone.”

Accordingly, Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

J. The Pending Claims Are Patentable Over Rothbard, Waugh, and Crowley

Applicants respectfully traverse the rejection of claims 78-80 and 85 under 35 U.S.C. § 103(a) for allegedly being unpatentable over Rothbard in view of Waugh and Crowley. As discussed above, both Waugh and Crowley fail to teach or suggest a method that involves topically applying the presently claimed carrier and biologically active protein, wherein the “carrier and the biologically active protein directly contact to form a non-covalent complex with the biologically active protein “ and wherein the biologically active protein “is not modified by covalent attachment to a negatively charged backbone.”

Rothbard does supply these missing elements. As noted above in the discussion concerning the § 102(b) rejection over Rothbard, Rothbard does not disclose the presently claimed carrier. Accordingly, Rothbard does not teach or suggest a method that involves topically applying the presently claimed carrier and biologically active protein, wherein the “carrier and the biologically active protein directly contact to form a non-covalent complex with the biologically active protein “ and wherein the biologically active protein “is not modified by

Accordingly, Rothbard, Waugh, and Crowley, either individually or in combination, fail to supply all the features of the instant invention. Applicants thus respectfully request reconsideration and withdrawal of this ground of rejection.

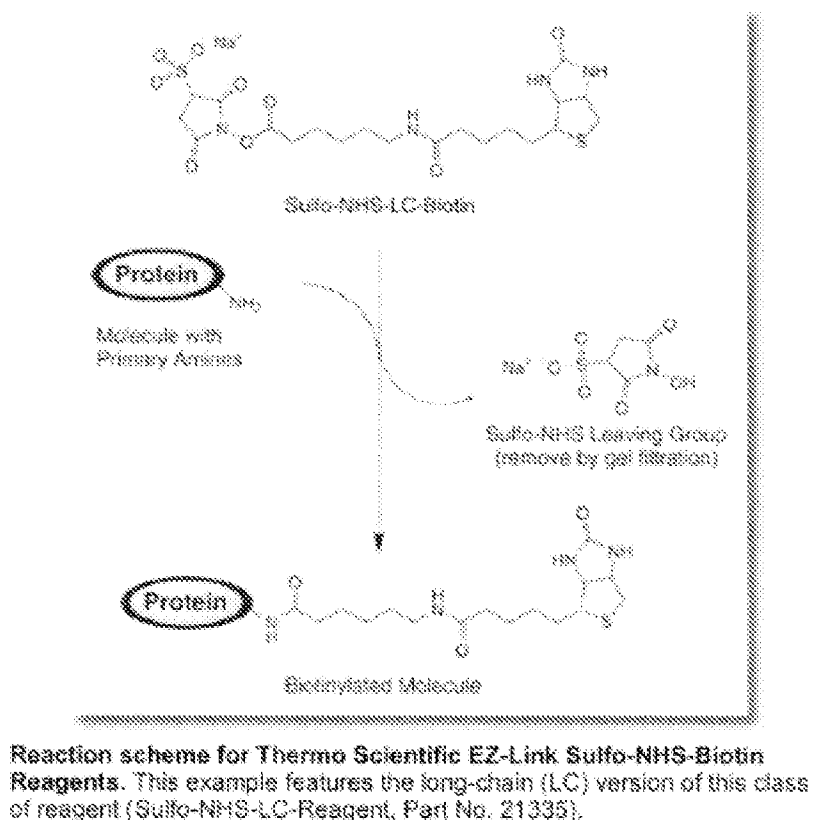
K. The Presently Claimed Invention Is not Obvious Over Waugh

In an Information Disclosure Statement filed on May 20, 2011, Applicants submitted to the USPTO a Written Opinion issued for a European counterpart application of a related case. In that Written Opinion, the European Examiner argued that the claims in that European counterpart application lacked inventive step over Example 4 of Waugh, a reference that is presently being relied upon by the Examiner to reject claims in this application.

In the interest of moving prosecution along, Applicants take this opportunity to discuss Example 4 of Waugh, even though no rejection has been issued in this case based on Example 4 of Waugh.

Applicants respectfully assert that Example 4 of Waugh does not render the presently claimed invention obvious. As noted above, Waugh discloses that proteins, such as botulinum toxin, must be covalently attached to a negatively charged backbone. The negatively charged backbone is used to promote complex formation with a positively charged backbone.

Example 4 of Waugh merely describes a variation of this approach. In Example 4, biotinylated insulin is delivered across skin using a carrier referred to as “KNR,” which Waugh describes as polylysine having attached efficiency groups. Unlike some of the other embodiments in Waugh, the insulin to be delivered is not covalently attached to a negatively charged polymeric backbone. Instead, the insulin is covalently modified by attaching separate sulfo-NHS-LC groups, as described in the reaction scheme below:



See Waugh, Example 4 and Pierce Protein Research Projects, “EZ-Link Sulfo-NHS-Biotin and Biotinylation Kits,” a reference submitted herewith in a Supplemental SB08 Form.

Example 4 of Waugh discloses that there is a 12-fold molar excess of biotin with respect to insulin, so that there are, on average, twelve biotin molecules attached to each insulin via the

mechanism shown above. **Critically**, one of ordinary skill in the art would have recognized, at the time the invention was filed, that biotin carries negatively charged in aqueous solution. See, e.g., Naujoks et al., Colloids and Surfaces A: Physiochem. Eng. Aspects 249 (2004) at page 71, col. 2, last paragraph (describing IgG-biotin stabilized droplets as carrying a negative charge). See also, George et al., Adv. Mater., (2006) Vol. 18, at p. 577-581 (specifically, see p. 577, col. 2, lines 11-13, describing the earlier study by Naujoks in 2004 as establishing that biotin is negatively charged in aqueous solution) (references submitted herewith with an SB08 form). Therefore, on average, each biotinylated insulin in Example 4 of Waugh carries about twelve negative charges.

In other words, Example 4 of Waugh merely shows that a protein can be functionalized by negative charges distributed discretely on the protein, as an alternative to attachment to a negatively charged polymeric backbone described in the other embodiments of Waugh. In any event, in both cases Waugh teaches that a protein must be covalently modified--either by attaching it to a negative charged backbone or to individual negatively charged groups like biotin -- in order to be able to associate the protein to a positively charged backbone carrier.

By contrast, the presently claimed invention recognizes, quite surprisingly, that no covalent modification with a negatively charged backbone is required to form the presently claimed non-covalent complexes. Accordingly, the presently pending claims are not obvious over Example 4 of Waugh. See MPEP § 2144.04, citing to *In re Edge*, 359 F.2d 896, 149 USPQ 556 (CCPA 1966) (stating that the omission of an element but retention of its function indicates non-obviousness).

Double Patent Rejections

As noted on pages 9 and 10 of this response, the Examiner has issued several provisional obviousness type double patenting rejections. Applicants respectfully request that the Examiner hold these provisional obviousness-type double patenting rejections in abeyance until the double-patenting rejection is the only rejection left in at least one of these applications. See MPEP 804(I)(B) (stating that “[t]he "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in at least one of the applications.)

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. 50-3732, Order No. 13720-105074. In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. 50-3732, Order No. 13720-105074.

Respectfully submitted,
KING & SPALDING, L.L.P.

Dated: May 26, 2011

By: /Joseph D. Eng Jr./

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